



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,863	02/08/2000	FREDERIC DONIE	BMD9974US	7240

7590

12/03/2001

MARILYN L AMICK
ROCHE DIAGNOSTICS CORPORATION
9115 HAGUE ROAD BLDG D
PO BOX 50457
INDIANAPOLIS, IN 462500457

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,863

Examiner

Bao Qun Li

Applicant(s)

DONIE ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17, 19, 23, 25, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 17, 19, 23, 25, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence letter

DETAILED ACTION

Claims 16-17, 19, 23, 25, 29 and 30 are pending.

Sequence requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Examiner has noted that the sequences listed in Table 1 and 2 on page 8 and 9 and sequences recited on page 13 fail to comply with the office sequence rules.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Response to Amendment

This is a response to the amendment, paper No. 11, filed May 28, 2001. Claims 15, 18, 20-22, 24, 26-28 and 31-33 are canceled. Claims 16, 17, 19, 23, 25, 29 and 30 are amended. Claims 16-17, 19, 23, 25, 29 and 30 are considered by the examiner.

Please note any ground of rejection(s) that has not been repeated is removed.

Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Claims 16, 19, 25, and 30 are still rejected under **35 USC § 112**, second paragraph on the similar ground as described in the previous office action.

Although Applicants amend the claims 16, 19, and 30 to define the epitope region II of HIV-1 subtype D isolate and epitope I region of HIV-1 subtype E isolate as an HIV-1 subtype E

isolate variant thereof (claim 16) or subtype D variant thereof (claims 19 and 30) in order to overcome the rejection. However, the metes and bonds of "a variant thereof" in claims 16, 19, 30 are not defined. The claims are interpreted in light of the specification; however, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants are suggested to point out the precise amino acid sequences that encode the epitope regions to overcome the rejection.

The rejection of claim 25 is still maintained because Applicants also fails to point out what is the precise sequence structure of epitope I and II of HIV-1 subtype O.

Claims 16-17, 19, 23, 25 and 29-30 are still rejected still rejected under **35 USC § 112**, first paragraph on the similar ground as described in the previous office action.

Applicants assert that the claims 16, 19 and 30 are amended; therefore, the rejection should be withdrawn. Applicants argument has been fully considered, however, it is not found persuasive for the reason that Applicants still fail to teach the precise sequences or consensus sequences of gp41 epitope I and II from all HIV subtypes of group M including the subtype A, B, C, D, F, O. Those sequences are particularly important to enable the scope of the claimed invention because the objection of the present invention is recited by the specification as "to provide an improves process for the detection of antibodies against HIV and particular HIV-1 subtypes (claim 16 citation of an immunoassay method for detecting of an antibody against HIV does not limited to any particular group of HIV-1 virus). This improvement process should ensure that especially the subtypes of the wildly spread group M can be detected specifically and clearly" (see specification second paragraph on page 3). In order to overcome the enablement rejection, Claims should particularly point out the precise sequences of the epitopes from different subtypes of HIV group M that are used in combination with disclosed epitope II of HIV-1 subtype D and epitope I of HIV-1 subtype E. Therefore, the rejection is still maintained.

Claim Rejections - 35 USC § 103

Claims 16, 17, 19, 23, 25, 29 and 30 are still rejected under **35 USC § 103** (a), on the similar ground as described in the previous office action.

Applicants argue that the combination of the teaching from DeLeys et al. and Charmaret et al. would led to an assay with two antigens of HIV group M and subtype D, which is not what

Applicants are claiming. Applicants claim the combination of Group D with Group M (not D) peptide.

Applicants' argument has been respectfully considered. However, it is not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies, i.e. the peptide of Group D are not recited in the rejected claims or disclosed in the specification. The method of Applicants claimed is to detecting the antibodies against HIV-1 by using the consensus sequence of an HIV-1 subtype D and an antigen from the epitope II region of gp41 of a different HIV subtypes of M group and mixture up antigen from epitopes I region of the consensus sequence of an HIV-1 subtype E isolate. The specification also only discloses the antibodies detected by using the antigen form the HIV-1 G group M's subtypes, such as subtypes A, B, c, D, D, O or E (Tables 1-3 on pages 8-9, Table 3.2 Evaluation of results on page 23, lines 12-27 on page 10 and 12-22 on page 13 of the specification). No group D of HIV-1 antigen peptide is recited. Nevertheless, there are no antigen peptide from Group D is disclosed and claimed. Therefore, the rejection is maintained.

New ground of rejection:

Claim Rejections - 35 USC § 112

Claims 16-17, 19, 23, 25, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 19 and 30 are vague and indefinite in that the metes and bonds of "a variant thereof" are not defined. The claims are interpreted in light of the specification, however, the specification fails to teach what the definition of "a variant thereof" is. Therefore, the claims render indefinite. In order to overcome the rejection, the precise amino acid sequence of the variant thereof should be point out in the said claims. This affects the dependent claims 17, 23, 25.

Conclusion

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

November 21, 2001


ALI R. SALIM
PRIMAry EXAMINER